Complete Summary

GUIDELINE TITLE

Prevention and management of obesity (mature adolescents and adults).

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Prevention and management of obesity (mature adolescents and adults). Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Nov. 94 p. [202 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Obesity

GUIDELINE CATEGORY

Diagnosis
Management
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Nutrition
Pediatrics
Preventive Medicine
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To increase awareness of obesity through documentation of body mass index (BMI)
- To improve the percentage of patients with BMI greater than or equal to 25 who were recommended appropriate treatment for obesity as per guideline
- To improve the outcome of the treatment for obesity
- To improve community (employers, schools) involvement in the prevention and treatment of obesity

TARGET POPULATION

Mature adolescents and adults

This guideline does not include the patient population of pregnant women or body builders/weight trainers.

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention/Diagnosis/Risk Assessment

1. Measure height and weight and calculate body mass index (BMI)
2. Assess for major and minor comorbid conditions including hypertension, cigarette smoking, peripheral vascular disease, type 2 diabetes mellitus, depression, eating disorders, etc.
3. Advise weight maintenance and manage other risk factors.
4. Assess readiness to lose weight

Treatment/Management

1. Follow the 5 As (Ask, Advice, Assist, Assess, Arrange)

2. Provide lower calorie balanced eating plan, encourage calorie reduction, and provide referral to a dietitian
3. Physical activity
4. Behavioral management and counseling including self-monitoring of weight, nutrition, and activity; stimulus control; cognitive restructuring; goal setting, social support, etc.
5. Pharmacologic therapy including:
    - Food and Drug Administration (FDA) approved medication, such as benzphetamine, diethylpropion, methamphetamine, phendimetrazine, phentermine, phentermine resin complex, sibutramine, orlistat
    - Nonprescription and natural medications containing the following substances: ephedrine, caffeine, benzocaine, chromium, phyllium, chitosan, and herbal compounds. Herbal preparations include ma huang (Ephedra sinica), St, John's wort (Hypericum perforatum), guarana (Paulinia cupana), kola nut (Cola nitida, Cola acuminata, and Garcinia cola) and others.
6. Surgical procedures including vertical banded gastroplasty, adjustable gastric band, biliopancreatic diversion, duodenal switch, and Roux-en-Y gastric bypass
7. Regular follow-ups

MAJOR OUTCOMES CONSIDERED

- Effectiveness of weight loss interventions (e.g., diet, physical activity, medication)
- Effect of weight loss interventions on prevention and management of type 2 diabetes mellitus and cardiovascular risk factors

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Additional descriptions of literature search strategies are not available.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of review period.

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group

Following the completion of the review period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary and a written response is prepared to address each of the responses received from member groups. Two members of the Committee on Evidence-Based Practice carefully review the input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of four questions: (1) Is there consensus among all ICSI member groups and hospitals on the content of the guideline document? (2) Has the drafting work group answered all criticisms reasonably from the member groups?

(3) Within the knowledge of the appointed reviewer, is the evidence cited in the document current and not out-of-date? (4) Is the document sufficiently similar to the prior edition that a more thorough review (critical review) is not needed by the member group? The committee then either approves the guideline for release as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Member groups may introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three-six months. At the end of the pilot test phase, ICSI staff and the leader of the work group conduct an interview with the member groups participating in the pilot test phase to review their experience and gather comments, suggestions, and implementation tools.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Committee on Evidence-Based Practice reviews the revised guideline and approves it for release.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for the prevention and management of obesity in mature adolescents and adults are presented in the form of an algorithm with 11 components, accompanied by detailed annotations. An algorithm is provided for Prevention and Diagnosis. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

1. Obesity is a chronic disease that is multi-factorial with complex political, social, psychological, environmental, economic and metabolic causes and consequences. Obesity affects essentially every organ system in the body. Health consequences increase across the body mass index (BMI) span, not just for the extremely obese. (Annotation #1)
2. Calculate the BMI; classify the individual based on the BMI categories. Educate patients about their BMI and their associated risks. (Annotation #1)
3. Effective weight management strategies are available and include nutrition, physical activity, lifestyle changes, medication, and surgery. (Annotation #8)
4. The physician should follow the 5 A's (Ask, Advise, Assess, Assist, Arrange). Physician intervention can be effective, the physician can have an important influence, and successful weight management is possible. (Annotation #8)
5. Weight management requires a team approach. Be aware of clinical and community resources. The patient needs to have an ongoing therapeutic relationship and follow up with a health care team. Weight control is a lifelong

commitment and the health care team can assist with setting specific goals with the patient. (Annotation #8)
6. Beyond their clinical role, primary care physicians should be aware of their role as a community leader, and a public health advocate. (Annotation #11)

Prevention and Diagnosis Algorithm Annotations

1. Measure Height, Weight, and Calculate BMI (Preferably Annually for Screening and as Needed for Management)

   Key Points:

   - Health consequences exist across the BMI span and obesity is a multi-factorial chronic disease.
   - Body mass index should be calculated preferably annually for screening and as needed for management.
   - BMI calculation extends to all age groups. Adolescents less than Tanner stage 5 and children should be evaluated by available growth charts.

   Calculate BMI

   Obesity is a chronic disease that is multi-factorial with complex political, social, psychological, environmental, economic and metabolic causes and consequences. Obesity affects essentially every organ system in the body. Health consequences increase across the BMI span, not just for the extremely obese. Calculate the BMI; classify it based on the BMI categories. Educate patients about their BMI and associated risks for them.

   Refer to Appendix A, "Body Mass Index Chart" in the original guideline document.

   Adults:

   BMI less than 18.5 (underweight)

   BMI 18.5-24.9 (normal weight)

   BMI 25-29.9 (overweight)

   BMI 30-34.9 (obese - class I)

   BMI 35-39.9 (obese - class II)

   BMI greater than 40 (extreme obesity - class III)

   Mature adolescents:

   Physiologically speaking, maturation refers to the tempo of sexual development during puberty. The physiologic progression of pubertal stages

proceeds in a definable sequence but the age of onset and the rate of progression exhibit significant inter-individual variability. Pubertal stages from pre-puberty to mature adult have been categorized by Tanner in 1962. Tanner identified 5 stages of maturation based on progressive changes in external genitalia.

For the purpose of this guideline, Tanner stage 5 will be considered physiologic maturity. The extension of guideline medication and surgery recommendations to this population is physiologically feasible. However, given the complexity of obesity variables and psychosocial issues, the use of medications and surgery in physiologically mature but younger adolescents needs to be discussed and decided within provider community practice standards.

Adults may be sub-classified using absolute values for BMI (ht/wt). These absolute cut-offs for BMI may also be used for the sexually mature (Tanner stage 5) fully grown adolescent. However, absolute cut-off values cannot be directly applied to all adolescent patients. Adolescence is characterized by variable growth rate and variable tempo for sexual maturation. This variability in height and body composition complicates the determination of absolute BMI cutoffs for a normally changing individual. Growth, maturation and ethnic differences also make it difficult to determine a definite chronologic age for using adult BMI criteria.

The normative value for pediatric and adolescent BMI is highly age dependent.

See Appendix B, "Body Mass Index-For-Age Percentiles" in the original guideline document.

Since BMI is based on height and weight, it reflects the underlying variability in these features at a given chronologic age. Given the confounding effects of growth and maturation, the traditional Pediatric approach to establishing normative values is to develop percentiles based on a reference population. The National Health and Nutrition Examination Survey (NHANES) has been done three times: NHANES I (1963-1970), II (1976-1980), III (1988-1991). More recently, Rosner, et al. combined data from nine United States studies, including NHANES II and III, on over 66,000 participants. From this data set they determined BMI percentiles for ages 5-17. BMI tables are presented for boys and girls with ethnic subsets: Asian, Black, Hispanic and White. United States weighted mean values are also provided.

In the pediatric literature, the "at risk" group has been defined as the 85th percentile. The 95th percentile has been used to identify the obese or grade 2 overweight individual. Specific cut-off values for a given gender, age and ethnic group are available from the previously mentioned percentile tables.

A BMI calculation is worthwhile in the growing patient because it provides a reference point for future comparison. Subsequent observations establish a relative trajectory for this index of obesity. Although there are no standards for rate of change of BMI per year, a rapid increase or decrease warrants clinical attention. The separation between 50th and 75th percentile is

approximately 2-3 BMI units for adolescent girls across ethnic groups. Adolescent boys have approximately 2 BMI units difference between these percentiles. An annual increase of greater than 3 units suggests excessive gain.

The clinical significance of an abnormal or rapidly changing BMI is assessed with the following in mind:

- BMI is not a direct measure of adiposity. It is a derived value that correlates well with total body fat and markers of secondary complications (e.g., hypertension and dyslipidemia)
- An abnormally high BMI does not address the distribution of body fat (i.e., central versus peripheral or visceral versus subcutaneous). Central or visceral fat carry greater risk for morbidity and mortality.
- Waist circumference (as recommended by the National Heart Lung and Blood Institute (NHLBI), see Annotation #2, Figure #3 in the original guideline document) provides an additional dimension for assessing visceral adiposity and clinical risk.
- Metabolic assessment is important in the patient at risk, especially if there is a positive family history for heart disease or type 2 diabetes mellitus.
- Refer to Table 1 in the original guideline document for clinical associations with adolescent obesity. Depression, anxiety, eating disorders and sexual abuse are also important clinical associations with adolescent obesity.

Evidence supporting this recommendation is of classes: D, R

2. Assess for Major and Minor Comorbid Conditions

Key Points:

- It is important to assess for other conditions as treatment decisions and outcomes may be influenced by their presence.
- Waist circumference greater than or equal to 40 inches for males and greater than or equal to 35 inches for females is an additional risk factor.
- Depression and eating disorders brief screenings should be conducted if appropriate.
- Assessment should include a complete medical history to identify medications that may induce weight gain or interfere with weight loss.

Comorbid Condition Assessment

Comorbid Condition	BMI			
	25 - 30	30 - 35	35 - 40	40+
0	Lifestyle changes	Lifestyle changes	Lifestyle changes	Lifestyle changes

Comorbid Condition	BMI			
	25 - 30	30 - 35	35 - 40	40+
	and behavioral management	and behavioral management. Consider drug therapy	and behavioral management. Consider drug therapy	and behavioral management. Consider drug therapy and/or surgical evaluation.
1-3 minor comorbid conditions	Lifestyle changes and behavioral management	Lifestyle changes and behavioral management. Consider drug therapy	Lifestyle changes and behavioral management. Consider drug therapy and/or surgical evaluation.	Lifestyle changes and behavioral management. Consider drug therapy and/or surgical evaluation.
Major comorbid conditions OR more than 3 minor comorbid conditions	Lifestyle changes and behavioral management. Consider drug therapy. *The Food and Drug Administration (FDA) approves drug therapy only for BMI greater than 27.	Lifestyle changes and behavioral management. Consider drug therapy.	Lifestyle changes and behavioral management. Consider drug therapy and/or surgical evaluation.	Lifestyle changes and behavioral management. Consider drug therapy and/or surgical evaluation.

Minor Comorbid Conditions

- Cigarette smoking
- Hypertension (BP greater than or equal to 140/90) or current use of antihypertensives
- Low-density lipoprotein (LDL) cholesterol greater than 130 mg/dL
- High-density lipoprotein (HDL) cholesterol less than 40 mg/dL
- Pre-diabetes*
- Family history of premature coronary artery disease (CAD)
- Age greater than or equal to 65 years for males
- Age greater than or equal to 55 years for females or menopausal females

Major Comorbid Conditions

- Waist circumference
- Established coronary artery disease
    - History of myocardial infarction
    - History of angioplasty
    - History of coronary artery bypass graft (CABG)
    - History of acute coronary syndrome
- Peripheral vascular disease
- Abdominal aortic aneurysm
- Symptomatic carotid artery disease
- Type 2 diabetes mellitus
- Obstructive sleep apnea

* The term pre-diabetes has recently been adopted by the American Diabetes Association and others, and refers to those who have a fasting plasma glucose of 100 mg/dL to 125 mg/dL inclusive, as well as those with a 2 hour post 75 gram oral glucose tolerance test value of greater than or equal to 160 mg/dL to 200 mg/dL.

Note 1: Treatment recommendations are meant only to be broad indicators; treatment should be individualized in each case based on the physician's awareness of the patient's unique conditions including age, functional status, desire for treatment, emotional stability, social support network and willingness to adhere to recommended treatment.

Note 2: Lifestyle changes are the cornerstone of management of overweight and obesity. These primarily focus on nutrition, and physical activity, as well as behavioral and psychosocial barriers that may interfere with adherence to lifelong self-care. The effectiveness of other types of therapy, such as pharmacotherapy and/or surgery is substantially increased in patients who understand the importance of lifestyle management and are able, with appropriate education and skills, to sustain a healthy lifestyle.

Other Conditions

Waist circumference is an additional risk factor for males measuring more than or equal to 40 inches, females more than or equal to 35 inches. While the guideline development group acknowledges potential difficulty implementing the measurement of waist circumference, evidence shows the

importance of measuring waist circumference because of increased cardiovascular risk.

Evidence supporting this recommendation is of class: D

Screening for Depression

The evidence showing the linkage between depression and obesity is mixed. Higher rates of depression have been found in severely obese people, especially younger women with poor body image. It is difficult to study whether the depression is secondary to the obesity or to existing comorbid conditions. Weight loss often leads to improvement of depression scores.

Depression is identified more often in obese women and teenagers and is less likely to be diagnosed in men. Depression in the elderly is often associated with weight loss while depression in younger females can be associated with weight gain.

Depression has been associated with poor weight loss outcomes. Bariatric surgery patients with poorly managed depression or anxiety are at greater risk for weight regain within the first five postoperative years. One explanation for this may be found in a line of research investigating biological pathways that link depressive symptomatology to increased adiposity and weight gain. Weight loss studies have often excluded people with depression. More studies to address this issue are warranted.

Evidence supporting this recommendation is of classes: B, C, D, R

Screening for depression can include asking the following questions.

Over the past month, have you been bothered by:

1. Little interest or pleasure in doing things?
2. Feeling down, depressed or hopeless?

If the patient answers "yes" to either one of the above questions, consider using a questionnaire to further assess whether the patient has sufficient symptoms to warrant a full clinical interview and a diagnosis of clinical major depression. An example of such a questionnaire is the PHQ-9 (Patient Health Questionnaire).

This should not be considered a comprehensive screening for depression, which is beyond the scope of this guideline. See the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical Systems Improvement (ICSI) guideline Major Depression in Adults in Primary Care for more information.

Screening for an Eating Disorder

Eating disorders, particularly binge eating disorder, may complicate the treatment of obesity.

Screening for eating disorders can include asking the following questions:

1. Do you eat a large amount of food in a short period of time like eating more food than another person may eat in, say, a two-hour period of time?
2. Do you ever feel like you can't stop eating even after you feel full?
3. When you overeat, what do you do? (e.g., Have you ever tried to "get rid of" the extra calories that you've eaten by doing something like: Take laxatives? Take diuretics [or water pills]? Smoke cigarettes? Take street drugs like cocaine or crank? Make yourself sick [induce vomiting])?

If the patient answers "yes" to any of the above questions, consider further evaluation or a referral to a dietitian or a behavioral health specialist who specializes in eating disorders or in health psychology and working with bariatric patients.

More comprehensive screening tools include the SCOFF, ESP, or EAT.

Screening for Medication Use That Contributes to Weight Gain

The assessment of the obese patient should include a complete medication history to identify medications that may induce weight gain or interfere with weight loss including antidiabetic medication (insulin, insulin secretagogues, metformin, alfa-glucosidase inhibitors, thiazolidinediones) and psychotropic drugs. For more information regarding medications associated with weight gain, refer to the original guideline document.

5. Advise Weight Maintenance and Manage Other Risk Factors

Key Points:

- It is important to address the issue of weight maintenance for those with BMI in the normal range.
- Weight management includes physical activity, nutrition, and behavior management strategies.

Successful weight management requires a lifestyle approach that integrates physical activity, nutrition, behavioral management and attention to psychosocial needs.

- First, encourage regular physical activity at recommended levels. Regular physical activity is strongly related to maintaining normal weight. In selecting types of physical activity, it is important to consider the age of the patient, musculoskeletal limitations and availability of exercise facilities.
- Second, provide structured lifestyle modification suggestions that include specific nutrition recommendations, educational sessions, and frequent contact with health-care providers such as a dietitian. Focus on calorie balancing, using a combination of decreased caloric intake with increased calorie expenditure. Include nutrition education (i.e.

interpreting food labels); managing restaurant and social eating situations; making healthy, nutritious food choices; using portion control; and recipe modification.

There is considerable evidence that individuals consuming low-fat, low-calorie diets are successful at maintaining weight loss for 12 months and longer. Data from the National Weight Control Registry demonstrates that successful weight-maintainers consume a low-calorie diet containing ~ 40 g fat (24% of calories), 200 g carbohydrate (56% of calories) and 70 g protein (19% of calories). A low fat diet (25-30% calories from fat) is considered the conventional therapy for treating obesity

- Third, encourage behavior management strategies that may include weekly weight checks, food journals, and monitoring daily routine that focuses on a balanced lifestyle. Balance includes: (a) eating a nutritionally-balanced breakfast soon after awakening and eating balanced meals at regular intervals thereafter, (b) incorporating fun physical activity into the day, and (c) scheduling the week to include rest, play, and social interactions along with work, school, and family responsibilities.

  Specific behavioral strategies to promote behavior change include: (a) self-monitoring some aspect of behavior which, in itself, typically results in behavior change; (b) non-food rewards and positive reinforcements; (c) reminders; (d) stimulus control (changing social or environmental cues that trigger eating behavior); (e) stress management and problem solving; and (f) enhancing a sense of self-efficacy.

Evidence supporting this recommendation is of classes: C, R

8. Assess Readiness to Lose Weight, Negotiate Goals and Management Strategy to Achieve Weight Loss. Refer to Risk Appropriate Resources as Needed

   Key Points:

   - Knowing the patient's readiness to change can help the provider understand a patient's level of motivation and how to tailor communication about weight loss.
   - Patients need to set realistic, achievable goals and be held accountable to practice new behaviors that produce and maintain weight loss.
   - Nutrition recommendations include calorie reduction by evaluating portion size and number of servings recommended in the United States Department of Agriculture (USDA) Food Guide Pyramid.
   - The physiological effects of physical activity greatly depend on the frequency, duration, and intensity of movement.
   - Pharmacotherapy, when used for 6 months to 1 year, along with lifestyle modification including nutrition and physical activity, can produce weight loss in obese adults.

- Bariatric surgery is indicated in carefully selected patients with a BMI greater than or equal to 40 or 35-39.9 and who are at a very high absolute risk for increased morbidity or premature mortality. Patients are to be motivated, well informed in disease management, psychologically stable, and accepting of operative risks.

The physician should follow the 5 A's (Ask, Advise, Assist, Assess, Arrange). Physician intervention can be effective, the physician can have an important influence, and successful management is possible.

- ASK about, and measure height and weight. Implement an office-wide system that ensures that for every patient, preferably on an annual basis, weight is measured, body mass index is calculated, and patient is educated on BMI and risk status.
- ADVISE to lose weight. In a clear, strong, but sensitive and personalized manner, urge every overweight or obese patient to lose weight.
- ASSESS readiness to lose weight. Ask every overweight or obese patient if he or she is ready to make a weight loss attempt at the time (e.g., within the next 30 days).
- ASSIST in weight loss attempt. Help the patient with a weight loss plan.
- ARRANGE follow-up. Schedule follow-up contact, either in person or via telephone.

Refer to the original guideline document for more detailed information on the 5 As.

Evidence supporting this recommendation is of classes: A, C

Management Recommendations Based on BMI/Risk of Disease

BMI	*18.5-24.9	25-29.9	30-34.9	35-39.9	≥40
Risk	Low	Minor	Moderate	High	Severe
N = Nutrition	N	N	N	N	N
P = Physical Activity	P	P	P	P	P
B = Behavioral Management	B	B	B	B	P
M = Medication		M**	M	M	M

BMI	*18.5-24.9	25-29.9	30-34.9	35-39.9	≥40
Risk	Low	Minor	Moderate	High	Severe
S = Surgery				S***	S

* In this group of patients, weight maintenance and prevention of obesity are key issues because a substantial proportion of these patients may become overweight/obese in the future.

** Patients considered for pharmacotherapy should have a BMI > 30 and no concomitant obesity-related risk factors or diseases, or a BMI > 27 with concomitant obesity-related risk factors or diseases.

*** In the presence of significant comorbid conditions, surgery may be indicated for patients with a BMI of ≥ 35.

See also Annotation #2, Table 2, "Comorbid Condition Assessment", in the original guideline document.

Nutrition (Balanced healthy eating plan or lower calorie balanced eating plan)

1. Encourage at least 5 servings of fruits and vegetables per day, whole grains with a fiber intake of 35 grams or more daily, less than or equal to 30% of calories from fat (7-10% as saturated and trans fat).
2. For weight loss, encourage calorie reduction by evaluating portion sizes and number of servings recommended.
3. Provide tips for managing eating in social situations, dining out, take-out foods, and food label reading.
4. Provide referral to a dietitian, nutritionist or structured medically supervised nutrition program if available.

Refer to the original guideline document for additional information on Nutrition Assessment and Therapy, including the following topics:

- Diet history or eating pattern history
- Nutrition assessment
- Nutrition recommendations
- Nutrition outcomes and goals

Physical Activity

1. Minimally, all patients should be encouraged to do at least 10 minutes of physical activity above what they are already doing each day and gradually increase the amount of time and then intensity of activity.

2. Ideally, all patients should meet the current recommendations made by the American College of Sports Medicine - 30 minutes of moderate intensity activity on most days per week.
3. Patients unable to do physical activity due to arthritis, injury, etc. should be referred for further evaluation and appropriate treatment in order to increase the patient's mobility.
4. Provide tips for adding small bouts of physical activity to daily activities (for example, taking the stairs, parking farther away, exercising while watching TV). Activity breaks from screens is also important.

Refer to the original guideline document for additional information on Physical Activity, including the following topics:

- Specific roles for physical activity in obesity
- Prevention of obesity
- Acute weight loss
- Long-term weight maintenance
- Metabolic fitness with or without weight loss
- Physical activity prescription
- Frequency
- Duration
- Intensity

Behavioral Management

1. Identify behaviors that may lead to increased weight gain (for example: stress, emotional eating, boredom, etc).
2. Help patients set specific, measurable, time-limited goals to decrease calorie intake and increase physical activity as appropriate.
3. Suggest patients weigh themselves weekly, and daily track the amount and type of food/beverages consumed and physical activity completed.
4. Provide support and encourage patients to also seek support from family, friends, and support groups in order to assist them with their eating, activity, and weight goals.

Refer to the original guideline document for additional information on Behavioral Management, including the following topics:

- Self-monitoring of weight, nutrition, and activity
- Teach life skills
- Additional behavioral modification strategies that play a key role in successful weight loss and maintenance including:
    - Stimulus control
    - Cognitive restructuring
    - Goal setting
    - Problem solving
    - Social support
    - Relapse prevention

Medications (Pharmacologic Therapy)

1. Sibutramine and Orlistat are safe for most patients when carefully monitored by a physician and may be part of a program for weight management or maintenance, which should include nutrition and physical activity when indicated.
2. Since the short-term use of drugs (< 3 months) has not generally been found to be effective, pharmacotherapy should only be included in the context of a long-term treatment strategy.

Refer to the original guideline document for additional information on Pharmacologic Therapy, including the following topics:

- Safety and adverse effects (see also Potential Harms field in this summary)
- Drug interactions (see also Potential Harms field in this summary)
- Efficacy
- Therapeutics
- Patient monitoring
- Nonprescription and natural medications

Surgery

1. Bariatric surgery is indicated in carefully selected patients: (a) with a BMI greater than or equal to 40, or (b) with a BMI of 35-39.9 and who are at a very high absolute risk for increased morbidity or premature mortality (see Annotation #2, Table 2 in the original guideline document). Patients are to be motivated, well-informed in disease management, psychologically stable, and accepting of operative risks.

Refer to the original guideline document for additional information on Surgical Management, including the following topics:

- Contraindications for surgery (see also the Contraindications field of this summary)
- Restrictive procedures, including:
    - Vertical banded gastroplasty
    - Adjustable gastric band
- Malabsorptive procedures, including:
    - Biliopancreatic diversion
    - Duodenal switch
    - Gastric bypass procedure
    - Roux-en-Y gastric bypass
- Surgical procedure selection process
- Resolution of comorbities
- Measurement of success and failure
- Adolescent bariatric surgery
- The patient process
- Obstructive sleep apnea
- Preoperative weight loss
- Cholelithiasis
- Special considerations
- Postoperative care
- Nutrition recommendations, including:

        - Gastric bypass diet progression
        - Strategies to maintain success with weight management
            - Protein
            - Nutrient deficiencies
            - Calcium and Vitamin D
            - Iron
            - Vitamin B12
    - Requirements that facilities should strive for
    - Minimum requirements for bariatric surgeons

11. Reassess Goals and Risk Factors and Counsel Regarding Weight Maintenance

    Key Points

    - Follow-up and long-term management of weight loss is crucial.
    - The primary care physician also may serve as a community leader and a public health advocate.

    Patients need regular follow-up for obesity, which is a lifelong problem in most cases. Regular follow-up conveys the message that the condition is important to the patient, and affords the opportunity for monitoring BMI as well as evaluation and management of any of the common complications that are often associated with obesity.

    A general recommendation of visits every 3 months is based on expert opinion, and may be varied to meet the particular needs of individual patients.

Definitions

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or

because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided in the original guideline document for Prevention and Diagnosis of Obesity.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations.")

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved awareness of obesity through documentation of body mass index (BMI)
- Improved outcomes in the treatment for obesity
- Improved community involvement in the prevention and treatment of obesity

POTENTIAL HARMS

Safety and Adverse Effects

Adverse side effects from the use of weight loss drugs have been observed in patients. Adverse effects are usually one of two types. There are dose-related minor effects that usually occur soon after beginning therapy. Infrequent, but potentially serious, adverse effects can also occur much later in the course of therapy. The initial adverse effects are usually a direct result of the drug's mechanism of action and are often mild and spontaneously resolve over time. Initial adverse effects can be avoided or minimized by:

- adjusting dosage and administration schedules
- identifying patients at high risk for adverse effects and selecting drug therapy accordingly
- providing patient education and monitoring for adverse effects at the beginning of therapy or when making dosage adjustments

Sibutramine

The adverse effects associated with sibutramine include abnormal electrocardiogram (ECG), hypertension, palpitations, tachycardia, dry mouth

(17%), headache (30%), insomnia (10%), anorexia (13%), constipations (11.5%).

Combinations of sibutramine and other serotonergic drugs should be avoided. If such a combination is used, patients should be informed about the signs and symptoms of serotonin syndrome, which include excitement, hypomania, restlessness, loss of consciousness, confusion, disorientation, anxiety, agitation, motor weakness, myoclonus, tremor, hyperreflexia, ataxia, incoordination, hyperthermia, shivering pupillary dilation, diaphoresis, emesis, and tachycardia.

Orlistat

The adverse events of orlistat are mainly gastrointestinal (GI) including oily spotting, flatulence, fecal urgency, oily stool, oily evacuation, increased defecation, fecal incontinence.

Orlistat has also been shown to reduce serum concentrations of fat-soluble vitamins (vitamins A, D, E, and K).

Combination Drug Therapy

The practice of combination drug therapy may increase the frequency of adverse events. There is also a lack of safety data on the use of combination therapy. Until data is available, it would be more prudent to use weight loss medications as single agents. Using the lowest possible effective dose may also reduce the chance of an adverse event.

Refer to Annotation Appendix E, Adverse Effects of FDA Approved Medications for the Treatment of Obesity and Annotation Appendix F, Drug Interactions of FDA Approved Medications for Treatment of Obesity for more information on adverse effects of these and other medications.

Complications of Surgical Procedures

- Vertical Banded Gastroplasty may cause obstruction; mortality rate: 0-1.6%
- Laparoscopic Adjustable Banding is associated with erosion 1.5% and slippage of the band 1.5%; mortality rate: 0.05%
- Biliopancreatic Diversion/Duodenal Switch is associated with protein malnutrition in 10% and diarrhea in 14%. There is also a significant incidence of marginal ulceration with this operation; mortality rate: 0 9%
- Roux Gastric Bypass may cause iron, vitamin B12 and folate deficiency, 30% incidence of dumping syndrome characterized by the presence of nausea, lightheadedness, the urge to lie down and palpitations. The most feared complications include leak. The incidence of marginal ulceration is 3%. Mortality rate: 1/250 1/1000. Likely causes of mortality include thrombotic or cardiac events or those related to technical complications of the operation.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to Medications

Sibutramine is contraindicated in patients with anorexia nervosa, concomitant monoamine oxidase inhibitor use, concomitant use of centrally acting appetite suppressants, use of other serotonergic drugs, coronary heart disease, congestive heart failure, stroke, arrhythmia, uncontrolled hypertension, history of substance abuse, pregnancy or lactation.

Orlistat is contraindicated in patients with cholestasis, chronic malabsorption syndrome, clinically significant gastrointestinal disease, patients at risk for fat-soluble vitamin deficiency.

Refer to Annotation Appendix E, Adverse Effects of FDA Approved Medications for the Treatment of Obesity for contraindications to other drugs.

Contraindications for Surgery

The decision to use surgery to manage morbid obesity requires the surgeon to weigh the risks against the sustained benefits of the surgical procedure. On occasion, the risk of not having bariatric surgery may be greater than the risk of a contraindication.

Strong Contraindications

1. Life-threatening multi-system organ failure
2. Uncontrolled or metastatic malignancy, or other serious medical illness where caloric restriction may compromise the patient
3. Uncontrolled human immunodeficiency virus (HIV) infection
4. Hypercarbic respiratory failure
5. Active systemic infection
6. Untreated endocrine dysfunction
7. Pregnancy and/or lactation
8. Current abuse of alcohol or other substances
9. Severe or unstable psychiatric illness that would prevent adjustment to the surgical procedure

Relative Contraindications

1. Reversible obstructive sleep apnea (that can be medically optimized before surgery)
2. Presence of severe liver, renal or gastrointestinal disease
3. Current tobacco abuse (nicotine addiction)
4. Binge eating at an average frequency of twice a week for the past six months
5. Problems with impulse control
6. Documented history of noncompliance (either medical or psychosocial)

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situations and any specific medical questions.
- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- Treatment recommendations are meant only to be broad indicators; treatment should be individualized in each case based on the physician's awareness of the patient's unique conditions including age, functional status, desire for treatment, emotional stability, social support network and willingness to adhere to recommended treatment.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

IMPLEMENTATION TOOLS

Clinical Algorithm
Quality Measures
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- Prevention and management of obesity (mature adolescents and adults): percentage of patients with obesity who have documentation in the medical record of discussion of weight management strategies, which may include nutrition, physical activity, lifestyle changes, medication or surgery.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Prevention and management of obesity (mature adolescents and adults). Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Nov. 94 p. [202 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Nov

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT SpecialtyCare, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, Hamm Clinic, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hennepin Faculty Associates, Hutchinson Area Health Care,

Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Health Care, North Suburban Family Physicians, NorthPoint Health & Wellness Center, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, St. Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Winona Health

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GUIDELINE COMMITTEE

Committee on Evidence-Based Practice

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted to fully inform readers.

Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

Sayeed Ikramuddin, MD receives grant support from Ethicon, Baxtar, W.L. Gore, and Stryker Endoscopy.

No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- ICSI pocket guidelines. April 2004 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2004. 404 p.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 12, 2005.

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